DEC 1 4 2011

# 510(k) Summary according to 807.92(c)

**Date prepared:** January 17, 2011
**Contact:** Jessee Hunt, President
4-Web Spine, Inc.
6629 Whispering Woods Ct.
Plano, TX 75024
972-841-6126

**Trade Name:** ALIF Spinal Truss System ® Interbody Fusion Device
**Product Class:** Class II
**Classification:** 21 CFR §888.3080 Orthosis, intervertebral fusion
**Product Codes:** MAX
**Panel Code:** 87

**Indications for Use:**
The ALIF Spinal Truss Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

**Device Description:**
The ALIF STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in three basic "footprint" sizes, small, medium and large. These sizes are available in 0, 6, 8 and 12 degree lordosis and each of these in 9 heights ranging from 8mm to 17mm in 1mm increments.

**Predicate Device(s):**
The ALIF STS® Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the 4-Web

Spine STS (K083894), the DePuy/AcroMed Brantigan Cage (P960025) and the Advanced Medical Technologies Distractable Wave Cage (K083626).

**Performance Testing:**
Preclinical testing performed on the 4-Web STS® Interbody Fusion Device included static compression, static compression shear, static torsion, dynamic axial compression, and dynamic compressive shear mechanical testing per ASTM F2077. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology.

**Design Changes to (K083894):**
Design changes include reduced struts diameter, removal of struts, rounding the top and bottom rim, adding domed contact surfaces, rounding the posterior edge, adding thread ports, increasing the number of lordotic angles and heights available as well as adding one additional cross strut under the posterior rims. The modified design underwent the same performance testing as to the previously approved device. The results indicate equal to or better than performance to the original design or other previously approved devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 14 2011

4-Web Spine, Inc.
% Silver Pine Consulting, Ltd.
Rich Jansen, Pharm.D.
13450 Guild Avenue
Apple Valley, Minnesota 55124

Re: K112316
Trade/Device Name: ALIF Spinal Truss System® Interbody Fusion
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class:. Class II
Product Code: MAX
Dated: December 08, 2011
Received: December 09, 2011

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number (if known): K112316

Indications for Use:

The ALIF Spinal Truss Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112316